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ERIZO, DARWIN P				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/601,127

Applicant(s)

SCHULER ET AL.

Examiner

Darwin P. Erez

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 12/10/08.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 53-55, 57 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,727,546 to Clarke et al.

(claim 53) Clarke discloses a method for aerosolizing a pharmaceutical formulation, the method comprising:

-providing a valve **27** (valve portion 24) within an airway (the interior space of the device shown in Figs. 2(a) – 2(c)) leading to the lungs to prevent respiratory gases from flowing to the lungs when a user attempts to inhale (Fig. 2(a) shows the closed position), and then permitting respiratory gasses to flow to the lungs (Fig. 2(b)) by opening the valve when a threshold actuating vacuum caused by the attempted inhalation exceeds the pressure of the spring biasing means **26**;

providing a flow regulator **23** within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases (as seen between Figs. 2(b)-2(c)), wherein the flow resistance through the flow regulator is low

Art Unit: 3773

when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases thereafter (see attached figure below); and

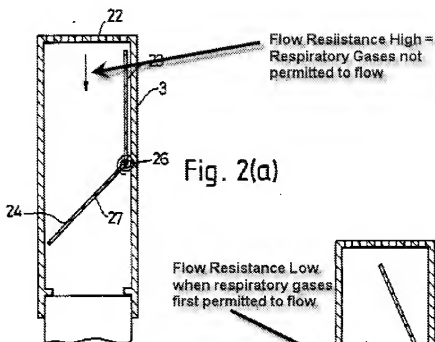
using the flow of respiratory gases to extract a pharmaceutical formulation from a receptacle **11** (shown in Fig. 1(a)) and to place said formulation within the flow of respiratory gases to form an aerosol.

(claim 54) Clark discloses the desired negative pressure created in the mouthpiece to be in the range of 0.1-20 mbar, which is equivalent to 0.1-20.29 cm H₂O (see col. 5, lines 2-4).

(claim 55) The flow regulator **23** is fully capable of limiting the flow of gas to a rate that is less than a higher rate.

(claim 57) The flow regulator **23** regulates the size of the airway.

(claim 59) The valve **27** and the flow regulator **23** are arranged in series.



Flow Resistance Low,
when respiratory gases
first permitted to flow.

Fig. 2(b)

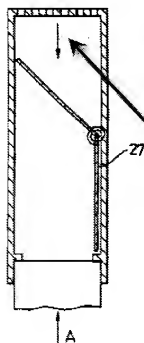
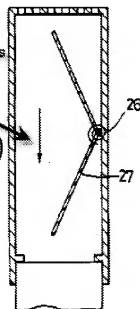


Fig. 2(c)

Flow Resistance becomes High
again when the user further
reduces the negative pressure
(col. 8, ll. 33-36)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. in view of US 6,116,237 to Schultz et al.

Clarke discloses a desired flow rate of between 20-250 l/min. Clarke fails to teach the specific flow rate of 15 l/min. However, Schultz discloses that a flow rate of 15-60 l/min is required to provide a better delivery efficiency of powder medicaments (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Clarke to include the flow rate of 15 l/min because certain dry powder medicament require a lower flow rate for better delivery efficiency of the medicament into lungs.

7. Claims 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al.

(claim 58) Clarke teaches the embodiment of the flow regulator **23** shown in Figs. 2(a)-2(c) as a vane. However, Clarke discloses various other embodiment for the flow regulator, including a duck bill valve shown in Fig. 9(a). These are disclosed as equivalent structures known in the art. Therefore, since these embodiments were art-recognized equivalent at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute one embodiment for the other.

(claim 60) Clarke teaches the valve **27** and the flow regulator **23** being arranged in series, as shown in Figs. 2(a)-2(c). Clarke fails to teach a parallel arrangement. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to modify the arrangement from a series arrangement to a parallel arrangement because Applicant has not disclosed that parallel arrangement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the series arrangement or the claimed parallel arrangement because both arrangements perform the same function of regulating air flow to the patient. Furthermore, the applicant has not provided any criticality to a "parallel" arrangement since the applicant discloses that the invention could either have a series or parallel flow arrangement.

Therefore, it would have been obvious matter of design choice to modify the invention of Clarke to obtain the invention as specified in claim 60.

Response to Arguments

8. Applicant's arguments filed 12/10/08 have been fully considered but they are not persuasive.

The applicant argued that the Clarke reference fails to disclose a threshold valve and flow regulator as claimed. This is still not found persuasive as the Examiner is maintaining the position that Clarke discloses structural elements that perform the recited functions.

With regard to the threshold valve limitation, the Examiner is interpreting vane 27 as said threshold valve. Vane portion 24 is urged by a spring 26 to a closed position, as shown in Fig. 2(a). Thus, vane portion 24 will "prevent respiratory gases from flowing to the lungs when a user attempts to inhale" if/when the initial inspiratory breath is not strong enough to overcome the spring bias. Once the inspiration is strong enough to overcome the spring bias, the vane portion 24 will "permit respiratory gases to flow to the lungs". The inspiration strength required to overcome the spring bias is the "threshold actuating vacuum".

With regard to the flow regulator limitation, the Examiner is interpreting vane portion 24 as said flow regulator. Vane portion 24 "varies the flow resistance through the airway to control the flow of respiratory gases". It is also noted that vane portion 24 provides a low flow resistance when the respiratory gases are permitted to flow, when the vane portion transitions from the position shown in Fig. 2(a) to Fig. 2(b). The position shown in Fig. 2(b) is interpreted as the position when "respiratory gases are

permitted to flow". Vane portion 24 increases the flow resistance when the inspiration rate is too much, as shown in Fig. 2(c).

Thus, the examiner maintains the position that the Clarke discloses the method as recited in claim 53.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/
Primary Examiner, Art Unit 3773